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**ADDENDUM TO THE ENGINEERING STUDY REPORT FOR
EVALUATION OF GEL BLEED FOR MENTOR GEL FILLED
IMPLANTS**

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1.0 PURPOSE

The purpose of this addendum is to document additional data from the testing performed in HS72.030826.01 Rev. 0 "ENGINEERING STUDY REPORT FOR EVALUATION OF GEL BLEED FOR MENTOR GEL FILLED IMPLANTS" (See Attachment 1)

2.0 DISCUSSION

After 8 weeks of conditioning and the completion of the test requirements for Gel Bleed in accordance to ASTM F703; Section X2 "FEASIBILITY PROTOCOL FOR GEL BLEED IN-VITRO TESTING BY MEANS OF A SILICONE DISK", the test samples from the three (3) Mentor Smooth Round Moderate Gel Implants P/N 3507350BC/Lot #259334 and 3 control samples remained in the oven for an additional 7 weeks at 110° F. Overall, the samples were conditioned for a total of 15 weeks.

As in HS72.030826.01 Rev. 0 "ENGINEERING STUDY REPORT FOR EVALUATION OF GEL BLEED FOR MENTOR GEL FILLED IMPLANTS", the test and control samples were removed from the oven, allowed to equilibrate at room temperature, and weighed at weekly intervals. The results are documented below in section 3.0.

3.0 RESULTS

As in HS72.030826.01 Rev. 0 "ENGINEERING STUDY REPORT FOR EVALUATION OF GEL BLEED FOR MENTOR GEL FILLED IMPLANTS" the following information will be documented in this report. (See Also Table 1)

- Records of all measurements of silicone disk weight for each time interval
- Records of temperature and humidity of laboratory at each time period
- Calculated average amount of gel per surface area diffusing out of test specimens
- Calculated average rate of gel diffusing out of test specimen
- Lot number.
- Part number
- Volume(s) of devices
- Type of product
- Sterilization method
- Sterilization lot numbers



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3.1 DATA ANALYSIS

The weekly data was compiled after the 15th week and formulated per ASTM F703 Section X2.10. The Average Weight Of Gel Diffusion Per Surface Area (W_g) and The Average Weight Of Gel Diffusion Per Surface Area Per Time Interval (R_g) were calculated as follows:

$$W_g = [(T_t - T_i) - (C_t - C_i)] / A_s$$
$$R_g = W_g / t$$

Where:

W_g = average weight of gel diffusion per surface area (g/cm²)

R_g = average weight of gel diffusion per surface area per time interval (g/cm²/t)

T_t = average weight of test discs at each time interval (g)

T_i = average weight of test discs at beginning of test (g)

C_t = average weight of environmental control discs at each time interval (g)

C_i = average weight of environmental control discs at beginning of test (g)

A_s = surface area of silicone disc (cm²)

t = cumulative time from beginning of test to each interval (weeks)



Table 1-Shell Down Gel Bleed Data

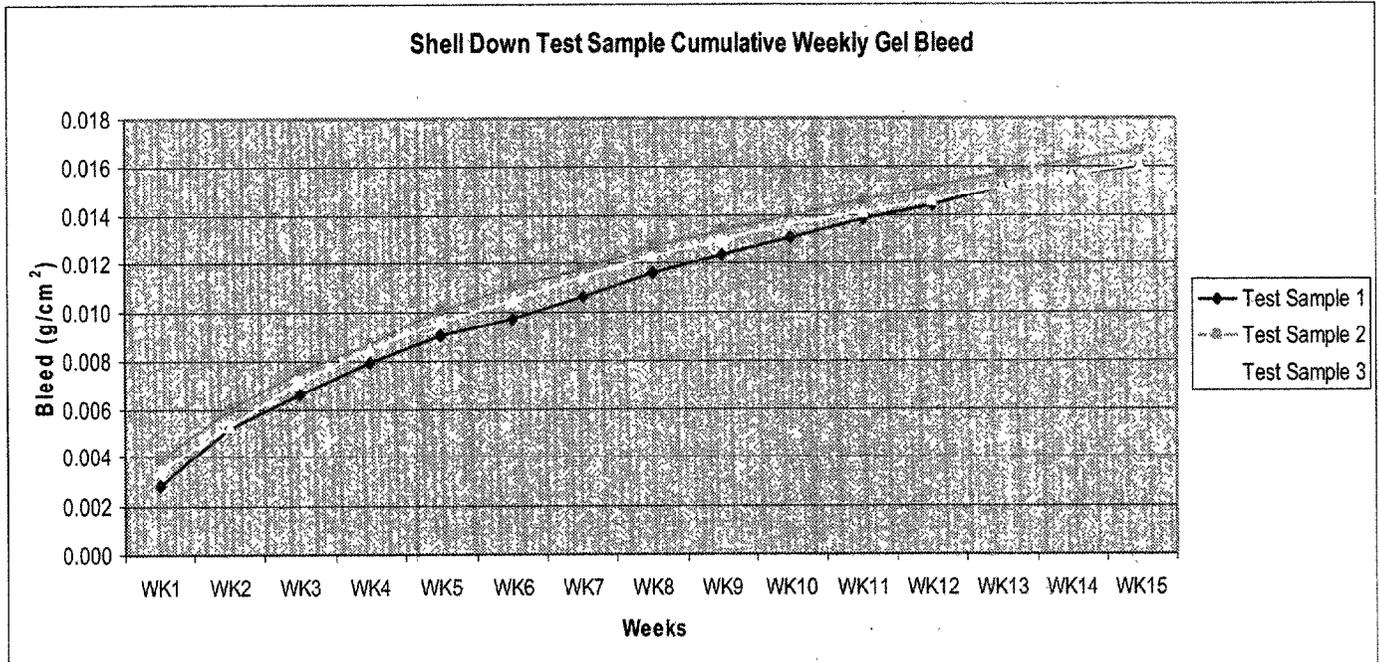
Type of Sterilization: Dry Heat		PN: 3507350BC					Scale EQ# B0151										
Humidity Control: 3 disc		LN: 259334					SP# 5107										
Test Samples: 3		Size: 350cc															
Control & Test Sample Area (cm ²)		19.6350															
Date	Thickness (in ²)	Sample Weight (g)															
		6/27/03	7/4/03	7/11/03	7/18/03	7/25/03	8/1/03	8/8/03	8/15/03	8/22/03	8/29/03	9/5/03	9/12/03	9/19/03	9/26/03	10/3/03	10/10/03
No of Days		0	7	14	21	28	35	42	49	56	63	70	77	84	91	98	105
Temp (C)		28.0	20.6	20.0	23.0	21.7	21.7	20.0	21.7	20.0	20.6	22.2	21.1	21.1	22.8	22.8	20.0
RH (%)		37.0	38.0	42.0	41.0	37.0	39.0	40.0	37.0	42.0	38.0	37.0	37.0	38.0	37.0	36.0	41.0
H1	0.12230	7.4616	7.4596	7.4616	7.4600	7.4602	7.4617	7.4620	7.4608	7.4614	7.4614	7.4625	7.4616	7.4627	7.4625	7.4634	7.4636
H2	0.12240	7.4617	7.4595	7.4614	7.4592	7.4594	7.4612	7.4610	7.4595	7.4598	7.4600	7.4609	7.4601	7.4612	7.4608	7.4616	7.4617
H3	0.12285	7.4967	7.4943	7.4963	7.4949	7.4948	7.4965	7.4965	7.4951	7.4959	7.4952	7.4968	7.4958	7.4969	7.4965	7.4974	7.4976
T1	0.12255	7.4691	7.5250	7.5708	7.5994	7.6249	7.6463	7.6604	7.6777	7.6967	7.7121	7.7253	7.7410	7.7521	7.7659	7.7767	7.7834
T2	0.12215	7.4500	7.5261	7.5676	7.5987	7.6206	7.6477	7.6674	7.6803	7.7000	7.7120	7.7242	7.7368	7.7477	7.7589	7.7687	7.7762
T3	0.12290	7.4861	7.5540	7.5898	7.6268	7.6522	7.6745	7.6924	7.7111	7.7279	7.7408	7.7540	7.7633	7.7733	7.7840	7.7926	7.8011
Tt		7.5350	7.5761	7.6083	7.6326	7.6562	7.6734	7.6897	7.7082	7.7216	7.7345	7.7470	7.7577	7.7696	7.7793	7.7869	
Ti	7.4684																
Tt-Ti		0.0666	0.1077	0.1399	0.1642	0.1878	0.2050	0.2213	0.2398	0.2532	0.2661	0.2786	0.2893	0.3012	0.3109	0.3185	
Ct		7.4711	7.4731	7.4714	7.4715	7.4731	7.4732	7.4718	7.4724	7.4722	7.4734	7.4725	7.4736	7.4733	7.4741	7.4743	
Ci	7.4733																
Ct-Ci		-0.0022	-0.0002	-0.0020	-0.0019	-0.0002	-0.0002	-0.0015	-0.0010	-0.0011	0.0001	-0.0008	0.0003	-0.0001	0.0008	0.0010	
Average Weight Of Gel Diffusion Per Surface Area (W _g)		0.00351	0.00550	0.00723	0.00846	0.00957	0.01045	0.01135	0.01226	0.01295	0.01355	0.01423	0.01472	0.01534	0.01579	0.01617	
Average Weight Of Gel Diffusion Per Surface Area Per Time Interval (R _g)		0.00351	0.00275	0.00241	0.00211	0.00191	0.00174	0.00162	0.00153	0.00144	0.00135	0.00129	0.00123	0.00118	0.00113	0.00108	



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Additionally, the data was charted to show cumulative gel bleed per week over the total conditioning period (See Figure 1).

Figure 1



This report has documented the additional raw data from the testing of Mentor Gel Filled Implant test samples. The report also documents the calculation of that data per the requirements for gel bleed testing listed in ASTM F703. No comparison to or development of specifications is required per ASTM F703 and will not be indicated in this report.

4.0 REFERENCES

- 4.1 GSL Special Project #5107
- 4.2 ASTM F703 "Standard Specification for Implantable Breast Prostheses"